

WHO WOULD HAVE THOUGHT IT?

Bandolier will soon be celebrating its third birthday and, like a three year old, we are developing. We try to make high quality systematic reviews intelligible for you (and us), and to make sure they have a clinically relevant output like NNT. We are less likely than we were to include results of single trials, because we, like you, want to see the results replicated before changing practice. We are able now to concentrate on systematic reviews because so many more are emerging.

Thank you for your suggestions

Firstly a big thank you to readers who tell us what you like and don't like. We do listen and try to respond. It also cheers us up on cold, wet November mornings in the leaky *Bandolier* portakabin. A few apologies are also in order. We get large amounts of correspondence and sometimes have problems answering all of the questions put to us. There will be occasions when we cannot answer the questions you pose, particularly if you ask us to do a systematic review on a topic. Just to remind you, some HTA sources reckon a systematic review costs £30,000 and takes two years as a minimum. *Bandolier* operates on loose change by comparison.

Web feet in water

Part of the catching up process has been to expand the *Bandolier* Internet correspondence section. This month sees another innovation - a paper submitted to *Bandolier* published on the Internet with a summary in the paper journal. We know that Internet connection is still problematic, but unlike Betamax, Internet is not vestigial technology. You will have to do it, and *Bandolier* is one reason to make the plunge.

Expanding into supply-side evidence

Bandolier has long wanted to expand its readership into the many pharmaceutical, diagnostic and medical device companies which interact with the NHS at all levels. They also need an evidence-base. *Bandolier* is pleased to announce that it has an arrangement with Hayward Medical Communications to explore this wider industrial readership for *Bandolier*. The arrangement in no way compromises our independence. All our readers can help in this worthwhile exercise. Next time you see anyone from industry ask if they read *Bandolier*, and if not, why not?

Bumper fun products

Bandolier is preparing its second annual - a bound and (slightly) updated version of all issues from 21 - 34. This should see the light of day in the Spring. We are also explor-

ing the possibility of providing a CD-ROM version of all *Bandolier* issues plus all other *Bandolier* publications that we have on the Internet, plus any other goodies that we can get free and put on the disc. The idea is to make it cheap, and constantly available on your computer. Watch this space!

Without them nothing happens

Bandolier has a wide and enthusiastic "family" which helps keep the show on the road. We need to thank them - the Pain Relief Unit in Oxford, the R&D and Clinical Effectiveness Directorates who arrange for most of you to get your copies of *Bandolier* every month, and our friends at Classic Press in Kidlington who put up with our constantly changing production numbers and distribution arrangements.

El Majombero's poser (poseur?)

Bandolier is curious about the evidence that the go-faster stripes sported by our athletic heroes actually improve performance. Those of you who have run for a bus in the last decade will be aware that mouth-breathing takes over from nose-breathing when you are exerting yourself. So why bother with go-faster stripes on your nose? Could it be potential advertising space? Or an evolutionary adaptation to scare your opponent?

EPIDURALS INCREASE CAESAREAN SECTION RATE

A systematic review of the influence of epidural analgesia during labour and the Caesarean section rate [1] provides an insight into how information collected from studies with different designs may be combined. It also answers the question: “how much extra risk is there of a woman having a Caesarean if she has an epidural?”

The review

The authors (from California) did a thorough review of the literature, including use of *Effective Care in Pregnancy and Childbirth* and contacting experts to locate studies. They read 230 manuscripts before settling on six for inclusion. Four of these were retrospective design - three reviewing all women delivered during a specified period, and one with a matched case control design. The other two were randomised controlled trials (RCTs).

Data extraction

The Caesarean delivery rate for epidural and non-epidural groups was extracted from the six reports.

Results

Bandolier took the data from each study and plotted the Cae-

sarean rate for epidural and non-epidural groups on a L'Abbé plot with the numbers of women included in each study and calculated odds ratio and NNT

There was a consistent increase in Caesarean section rate in women having epidural analgesia. The overall weighted difference was 10%, generating an NNT of 10 (95%CI 8.4 - 13), with an odds ratio of 2.6 (2.1 - 3.2).

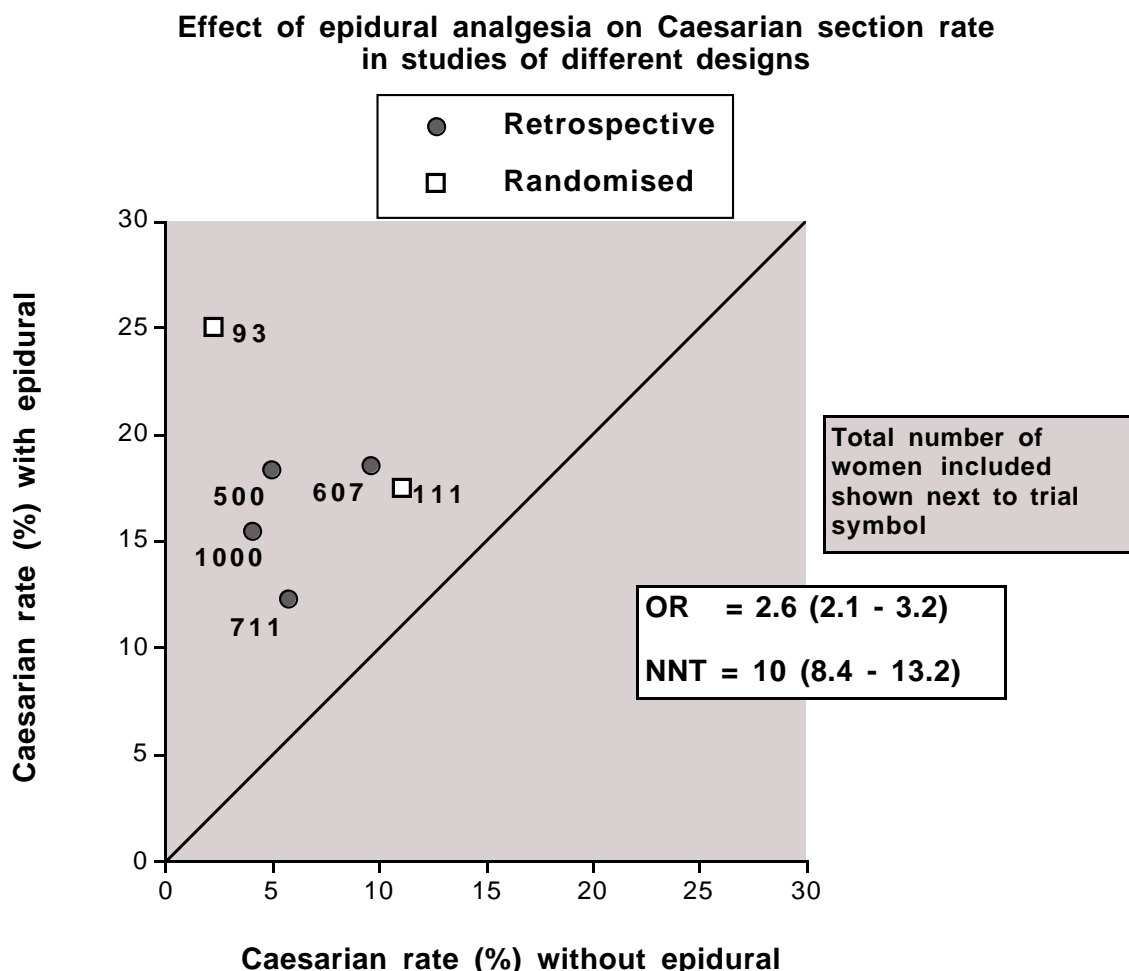
This means that for every 10 women in labour having epidural analgesia, one more will have a Caesarean section, who would not have done had they had another form of analgesia.

Comment

The NNT of 10 provides a figure which can be used by women and their carers in making choices about their labour. It was interesting that in this case both randomised and non-randomised designs produced the same estimate of effect. The paper discusses the issue of more complicated deliveries, and private and state health care, without making any startling conclusions. It is a useful read.

Reference:

- 1 SC Morton, MS Williams, EB Keeler, JC Gambone, KL Kahn. Effect of epidural analgesia for labor on the Cesarean delivery rate. *Obstetrics & Gynecology* 1994 83:1045-52.



CHANGING ORAL SURGERY

The use of randomised trials in surgery is becoming more common to demonstrate the effectiveness (or otherwise) of new surgical techniques. What is uncommon is a randomised trial to elucidate problems with operative methods that may give rise to uncommon but serious adverse events. We are grateful, therefore, to Derek Richards of Berkshire Health for making us aware of a recent study [1] from Sheffield.

Lower third molar removal

This is one of the most common UK oral surgery procedures. It is not without morbidity. Apart from pain, swelling and the like, possible nerve damage is a particular concern.

Several nerves may be affected temporarily and sometimes permanently. The rate of nerve damage is low, but for one nerve there is a great deal of variability in reported problems. One of the nerves to the tongue is reported to be subject to temporary damage in 0% to 25% of operations in 18 reports [1], and permanent damage (undefined) in 0% to 2% of operations.

One particular operative technique using a tool called a Howarth's elevator is intended to protect the lingual tissues and nerves in lower third molar removal, but there was concern that it might be responsible for higher rates of lingual nerve injury.

Randomised Trial

Robinson & Smith from the School of Clinical Dentistry at Sheffield carried out a randomised trial of operations with and without the Howarth's elevator to test its association with lingual nerve damage. Patients were allocated randomly to either operation.

They were seen at one week, and questioned about any subjective alteration in sensation from the lower lip or tongue. If

any alteration was reported, patients were seen at a special clinic where sensory testing was carried out. If no recovery of sensation occurred by 4 months, the lingual nerve was explored surgically and repaired if necessary.

Results

There were 771 operations, of which 378 used a Howarth's elevator. In the 393 where Howarth's was avoided, there were four operations in which the operator felt that visibility and access was inadequate and the Howarth's elevator was needed. The two groups were substantially similar.

The incidence of nerve damage in each operation type is shown in the table. Sensory disturbance from inferior or alveolar nerves was not different between the two operation types. The incidence of lingual nerve disturbance was much higher in the operations using the Howarth's elevator.

There were 26 affected persons compared with three in the control group; a significantly greater incidence. The NNT was 17, meaning that for every 17 patients who have a third molar removal with a Howarth's elevator, one will have temporary lingual nerve damage who would not have if the Howarth's elevator not been used.

Of the 26, 23 had progressive recovery over seven months. Three had permanent damage with complete anaesthesia and no evidence of recovery by four months. Exploratory surgery showed partial (one case) or complete (two cases) division of the nerve. The one case of complete anaesthesia in the non-Howarth's group had complete nerve division. There was no significant difference between permanent damage rates between the operative groups. The point estimate for the NNT was 100 and the low estimate of the 95% confidence interval was 64.

| Nerve damage | No Howarth's elevator used | Howarth's elevator used | Odds ratio (95% CI) | NNT (95% CI) |
|--|----------------------------|-------------------------|---------------------|--------------|
| Inferior or alveolar sensory disturbance | 17 | 12 | 1.5 (0.7 - 3.1) | 100 (24 - ∞) |
| Temporary lingual nerve damage | 3 | 26 | 5.4 (2.6 - 11) | 17 (11 - 29) |
| Permanent lingual nerve damage | 1 | 3 | 2.8 (0.4 - 20) | 100 (64 - ∞) |

Adverse events - and especially those that are uncommon but serious - are difficult to handle. Randomised trials which explore the problem are uncommon. This study showed an association between the use of an operative tool - the Howarth's elevator - and temporary damage to the lingual nerve.

How do we interpret these data? With caution: not because the study was flawed, but because different rules apply when we look at information about adverse events. We have a definite association with temporary damage to the lingual nerve - and temporary damage is likely to prove permanent in some fixed but indeterminate proportion of patients. Our best estimate at the moment is that in 3 of 26 (or 1 in 9) patients temporary nerve damage will turn out to be permanent. The rate of temporary nerve damage is eight times higher using a Howarth's elevator.

The other issue is one of significance. Do we care about formal statistical testing here for permanent nerve damage? Is the formal 95% confidence interval too conservative when looking at damage? Is the key figure, the one which puts us on our guard, the low estimate of 64 for the NNT for permanent nerve damage? That could be the correct figure.

The safe conclusion, as Robinson & Smith suggest, is that the use of a Howarth's elevator is contraindicated, and for the majority of cases lingual retraction should be avoided.

Reference:

- 1 PP Robinson, KG Smith. Lingual nerve damage during lower third molar removal: a comparison of two surgical methods. *British Dental Journal* 1996 180: 456-61.

Most of us will, from time to time, come across some interesting or amusing report which is just that bit different from usual. *Bandolier* vividly recollects a study in *Nature* (reference, alas, forgotten) which described the powerful anti smoking effect of alcoholic extracts of fresh barley shoots consumed in orange juice compared with drinking "screwdrivers". Why did we never manage to get out into the Oxfordshire fields, pick some barley shoots and do the 'definitive screwdriver study'?

So just in case *Bandolier* gets labelled with being "too techy", we thought we would open an "Old Curiosity Shop" for some of those interesting findings. In the next few months we will carry some stories, with different levels of evidence, and invite our readers to give us their favourite papers from the past with a difference.

Evidence-based budgerigars

A study reported in 1974 [1] on the psychotherapeutic value of giving budgerigars to old people. The authors started with the premise that old people can suffer from periods of social isolation which can lead to substantial psychiatric deterioration - the "isolation desocialisation syndrome". While they knew of some substantial work on the beneficial effect of pets on all ages, they were unaware of controlled studies, so they did one.

Budgerigars and begonias

There were five groups, but with only six old people aged between 75 and 81 years in each. Each elderly person was interviewed by a psychologist and a social worker and were asked a series of 22 questions about their life and attitude. Questions like "Do you have feelings of being fed up?" and "Do you feel time drags?" Favourable rapport was established by allowing each old person to choose a small gift, like a torch or a tray.

At this stage five interventions were set up:-

- 1 Give a budgerigar, cage, tray and bird food to six people who had a TV set.
- 2 Give a begonia to six people who had a TV set.
- 3 Give a budgerigar, cage, tray and bird food to six people who had no TV set.
- 4 Give a begonia to six people who had no TV set.
- 5 Control group of six people, half of whom had a TV set.

The questionnaire was administered again, five months later, and items were marked as no change, favourable change or unfavourable change.

However, there were some problems:-

- Six of 18 old people refused a budgerigar - mainly because they didn't like seeing birds in cages. None of the old people offered a begonia refused.
- Some of the budgerigars died within six weeks of place-

ment - but most of the subjects either had another bird given them or bought one themselves.

- At the time of the follow up visit only just over half of the old people could be assessed. Some had died, some had moved, and some just couldn't be contacted. So analysis was on half the original number of subjects.

Results

All 12 old people who had budgerigars had given the birds names, and insisted on making arrangements for food and so on. Some had made elaborate playgrounds and many taught the birds to speak. It was not reported whether similar attention was given to the begonias.

Having or not having aTV set made no difference, and we have combined the data from the questionnaire scores. At five months the controls had an overall unfavourable change in questionnaire scores, people given begonias had no overall change, but those given budgerigars had dramatically favourable changes in questionnaire scores.

Comment

This trial was neither randomised, nor did it have particularly large numbers. It did show a big efect and tried hard to

establish that the fact of the trial did not confound the efect of the budgerigar. The authors comment that it wasn't always so much the budgerigar itself, but the focus it made for discussion during social visits. For some of the elderly people the budgerigar stimulated visits, from local children, for instance, who came to teach the bird their names.

Evidence-based dogs

Alert readers will have noticed that the word random was missing from the budgerigar case. That cannot be said from an excellent randomised trial of the value of service dogs for people who need wheelchairs and published in JAMAearlier in 1996 [2].

Trial

Individuals who had been wheelchair mobile for at least two years and who had expressed an interest in a service dog were contacted in several US States. All had ambulatory motor impairment and many had additional problems.They were matched in pairs on criteria of age, sex, race, marital status and the nature and severity of the disability

Individuals within the 24 pairs were then randomised to receive a dog immediately, or 13 months into the programme.

Dogs were initially raised in a family environment and then paired with a person with a disabilityIndividualised training was then given to expand the dogs' ability to meet the unique needs of its human partner Total training time was six to twelve months.

Scoring

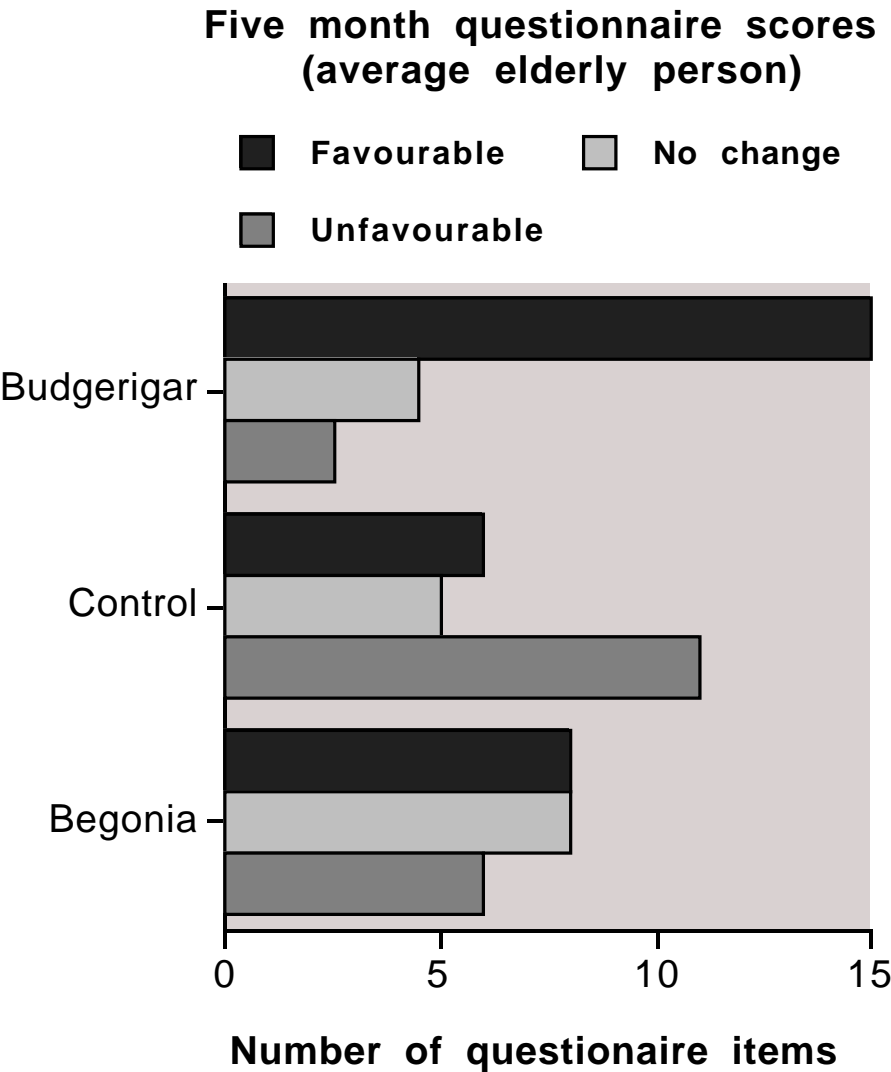
Lots of different scores were made at six monthly intervals.*Bandolier* concentrates on three - a self esteem score, and the number of hours of paid and unpaid assistance the individuals in the study needed.

Results

Dramatic changes took place after six months and were fully realised by twelve months. Self-esteem scores soared (as did psychological well-being, school attendances and employment), and the number of hours of assistance needed (paid and unpaid) plummeted. The same changes were seen in the control group as soon as they began working with a dog, while no changes occurred in the year they were waiting for one.

Comment

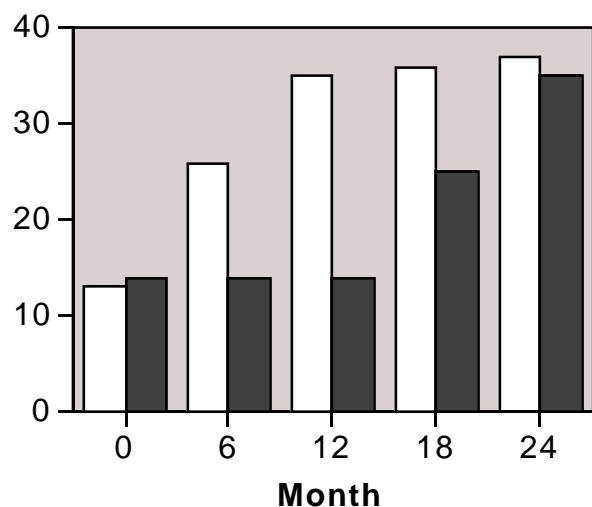
This is superb trial, showing what can be done with intelligence and persist-



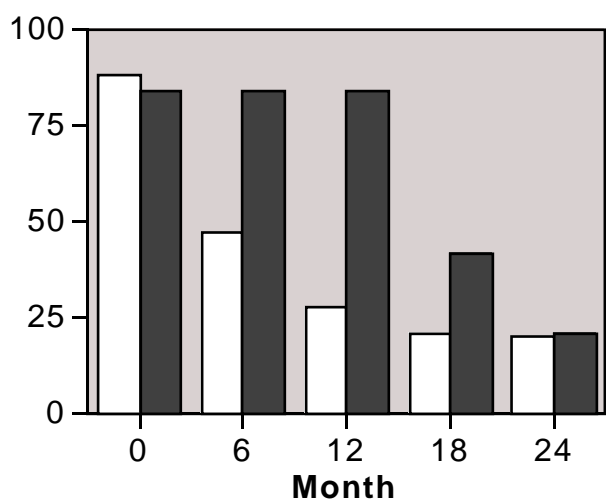
Service dogs introduced at

□ 0 months ■ 12 months

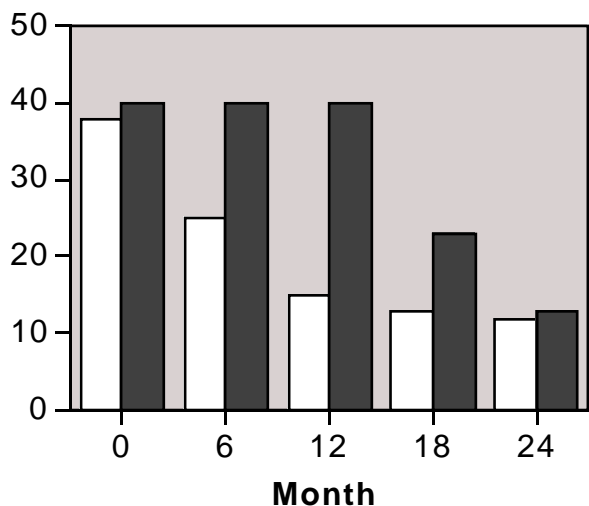
Self-esteem score



Biweekly hours of paid assistance



Biweekly hours of unpaid assistance



ence. There is even an economic analysis, also well done, which shows discounted eight-year savings of about \$90,000. Eight years is about the effective life time of a service dog before they begin to get old themselves and deserve retirement.

What *Bandolier* particularly liked in this paper was the way it ended, with a quote from one of the disabled people who took part in the study

"With my [dog], I feel safe and capable, and I am no longer afraid of the future. Everyone needs someone to care for, and we care for each other with dignity".

References

- 1 RA Mugford & JG M'Comisky Some recent work on the psychotherapeutic value of cage birds with old people. In *Pet Animals & Society* (RS Anderson, Ed) Ballière Tindall, London, 1975, pp54-65. ISBN 0 7020 05398.
- 2 K Allen, J Blascovich. The value of service dogs for people with severe ambulatory disabilities: a randomised controlled trial. *Journal of the American Medical Association* 1996 275: 1001-6.

CORRESPONDENCE

Response to Dr Down - Shop floor epidemiology

Down asks whether there is any research linking roads and respiratory health. There is. Edwards and colleagues found that children admitted to hospital with asthma were more likely to live in an area of Birmingham with a high traffic flow than were control children [1]. Elliott and colleagues, by contrast, found that asthmatic cases, defined as needing regular medication, were no more likely to live by main roads than were nonasthmatic controls [2]. Elliott and colleagues see these findings as contradictory, but perhaps asthma prevalence is unaffected by the roads and asthma severity is. Waldron and colleagues found that the prevalence of asthma in East Surrey was lower near the M25 than further away [3].

Proxy measures

Roads, of course, are a proxy for the amount of air pollution to which people are exposed. Schwartz found that more cases of croup, but not bronchiolitis presented to hospital when the level of nitrogen dioxide and particulates was higher [4]. It is hard to disentangle weather effects from this as weather is a major influence on the concentration of outdoor air pollution. The study cannot determine whether incidence or severity is affected.

Study findings

A Finnish study found that upper respiratory infections (URTIs) of all types were more common in toddlers in a polluted city than in two cleaner cities: odds ratio (95% confi-

dence intervals) were 2.0 (1.3-3.2) [5]. Toddlers in the most polluted parts of the polluted city had an odds ratio of 2.0 (1.0-4.0) for URTIs, compared to those in the less polluted parts. A study in Japan found that allergic rhinitis was more common in polluted areas and in areas with high concentrations of cedar pollen, but was most common in areas with high pollution and high cedar pollen levels [6].

In summary, we know that pollution from vehicles can exacerbate respiratory conditions, but we do not know whether it also affects the incidence, although the Japanese results suggest it might.

What Dr Down could do

It would be hard for Dr Down to study this problem in his/her practice. S/He could do a time series study like Schwartz. If s/he had access to daily pollution measures, s/he could examine the number of consultations in relation to the pollution level: a tricky statistical problem. Another approach is to compare his/her practice to one or more control practices away from the motorway to see if the number of consultations is different.

The difficulty here is knowing whether the differences in consultation rates are due to the pollution, or some other characteristic of the patients or the practice style. Studies of the effects of air pollution usually require large numbers of people and are best done using a population sample, rather than a sample of consulters.

[Mystery note: *Bandolier* apologises for losing the name and address of the reader who wrote this piece. Please let us know so we can acknowledge you properly]

References

1. Edwards J, Walters S, Griffiths RK. Hospital admissions for asthma in preschool children: relationship to major roads in Birmingham, United Kingdom. *Arch Environ Health* 1994;49:223-7.
2. Livingstone AE, Shaddick G, Grundy C, Elliott P. Do people living near inner city main roads have more asthma needing treatment? Case control study. *Br Med J* 1996;312:676-7.
3. Waldron G, Pottle B, Dod J. Asthma and the motorways—one District's experience. *J Publ Hlth Med* 1995;17:85-9.
4. Schwartz J, Spix C, Wichmann HE, Malin E. Air pollution and acute respiratory illness in five German communities. *Environ Res* 1991;56:1-14.
5. Jaakkola JJ, Paunio M, Virtanen M, Heinonen OP. Low-level air pollution and upper respiratory infections in children. *Am J Public Health* 1991;81:1060-3.
6. Ishizaki T, Koizumi K, Ikemori R, Ishiyama Y, Kushibiki E. Studies of prevalence of Japanese cedar pollinosis among the residents in a densely cultivated area. *Ann Allergy* 1987;58:265-70.

CONSORT

Bandolier has commented on the sources of bias that have been found in clinical trials due to lack of randomisation or blinding (see *Bandolier* 17). In 1994 two groups independently published proposals for requirements for reporting randomised trials [1, 2]. These groups have got together, and have produced a unified statement [3], which was summarised in a BMJ editorial by Doug Altman [4]. This is the Consolidation of the Standards of Reporting Trials, or CONSORT statement, of which much, rightly has been made.

What is most important is that the major medical journals including the BMJ, Lancet and JAMA are going to require authors of clinical trials to conform to these reporting guidelines from January 1 1997.

This is not the only initiative to improve reporting of clinical science. The two top clinical biochemistry journals, *Clinical Chemistry* in the US and *Annals of Clinical Biochemistry* in the UK will, also from January begin asking authors to conform to standards of reporting of diagnostic tests, featured in *Bandolier* 26.

These are important changes that will help us feel confident about trials we read.

References:

- 1 Standards of reporting Trials Group. A proposal for structured reporting of randomized controlled trials. *Journal of the American Medical Association* 1994 272: 1926-31.
- 2 Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature: a position paper *Annals of Internal medicine* 1994 121: 894-5.
- 3 C Begg, M Cho, S Eastwood et al. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *Journal of the American Medical Association* 1996 276: 637-9.
- 4 D Altman. Better reporting of randomised controlled trials: the CONSORT statement. *British Medical Journal* 1996 313: 570-1.

MORE ON VERUCCAS AND WARTS

The *Bandolier* 31 article on veruccas and warts has been the source of much *Bandolier* correspondence. There is a wide disparity of views out there, on how big the problem is, to how and when to treat, if at all. Randomised trials show that freezing warts can be effective (*Bandolier* 31), but Dr Bridger from Bromley and Professor Bantavala from Guy's and St Thomas' do not think treatment is always appropriate. They sent *Bandolier* a paper on the appropriate management of warts in the community

The paper is reproduced in full on the *Bandolier* Internet pages. They give much useful data on prevalence, incidence and natural history and the main points they make for appropriate management are given below.

Appropriate management

Bridger & Bantavala make the case that;

- Cutaneous warts are unsightly but harmless and transient.
- Treatment is unnecessary.
- When warts cause disability or difficulty in performing tasks, first line treatment is the application of a wart paint at home.
- Guidelines should be developed for the management of cutaneous warts in the community and shared with schools and those who advise schools.
- Appropriate mechanisms for educating health care professionals on the management of warts should be established.
- Funding of cryotherapy treatment of warts should be reduced.

Verrucas and games

A letter from Dr Dudley C Hubbard, Rochester

I read the article with interest as the treatment and control of verrucae has been an area of endeavour with me for many years. Unfortunately I have no controlled or carefully analysed data to present but over 25 years experience as the main treater of these in our practice of over 10,000 patients. Until the advent of liquid nitrogen available to general practitioners, we used an old Hyfrecator to diathermy the ones that didn't respond to topicals and paring, to which many did respond. Between 1972 and 1992 we used the Hyfrecator about 800 times; we keep a record of cases done. The total number seen and treated must have been several thousand on this basis.

At one stage I had conclusive proof of transmission at one particular school. I became aware of a preponderance of the verruca club from one school. When I checked I found that almost half of the then current group came from one school. We have pupils spread across some seven secondary schools close to the surgery. I felt that this was more than chance and investigated further I discovered that one particular PE mistress did not believe verrucae were important, nor catching, so insisted all pupils did bare foot gym and dancing on polished wood flooring. No precautions were taken whatsoever I insisted that this be stopped, encountered resistance, but

with the backing of the county council schools PE inspector, had all active cases covered up and parents' rights to insist on PE in gym shoes re-instated. The epidemic disappeared in about 3 months, returning to the usual sporadic case pattern we see in all the schools.

I cannot prove whether the infection was occurring in the changing rooms or in the gym, but as all schools inevitably have bare foot youngsters in changing rooms, I feel the gym floor was almost certainly the source of cross transfer. The risk of minor trauma from the floor would seem to support the theory that skin abrasions are the entry route.

CLINICAL EFFECTIVENESS

The NHSE has produced a "really useful" resource pack to provide details about sources of information on clinical effectiveness. It is full of details about where to get good information, who to contact in academic centres and contacts in different fields.

It has a neat section on critical appraisal, and how to make sense of evidence about clinical effectiveness. The 10 questions about making sense of a review are worth having to hand. *Bandolier* might quibble about a few minor points of process, but it encapsulates the rules that *Bandolier* tries to follow when examining reviews for inclusion in these pages.

Worth getting from Health Publications Unit, Two-Ten Communications, PO Box 410, Wetherby LS23 7LN. Fax 0990 210266 (and yes, we checked, it doesn't have a 1 in the code).